Henry C. Su (SBN 211202; suh@howrey.com)
Katharine L. Altemus (SBN 227080; altemusk@howrey.com)
HOWREY LLP
1950 University Avenue, 4th Floor
East Palo Alto, California 94303
Telephone: (650) 798-3500
Facsimile: (650) 798-3600

Robert Ruyak
Matthew Wolf
Marc Cohn
HOWREY LLP
1229 Pennsylvania Avenue, NW
Washington, DC 20004
Telephone: (202) 783-0800
Facsimile: (202) 383-6610

Attorneys for Plaintiffs
HOLOGIC, INC., CYTYC CORP. and HOLOGIC L.P.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

DECLARATION OF MARTIN E. KEISCH, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m
Room: Courtroom 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Martin E. Keisch, M.D., declare and state as follows:

1. I make this declaration based on my personal knowledge, training and experience, and if I were to be called to testify, I could and would testify competently about the subject matter set forth below.

2. I am a board-certified radiation oncologist. I am currently president of Cancer HealthCare Associates (CHCA) and medical director of radiation oncology at Cedars Medical Center in Miami, Florida.

3. I have extensive expertise in breast, prostate and GYN brachytherapy. I currently serve as an investigator in the Mammosite Multicenter DCIS trial and the Mammosite Registry trial for the American Society of Breast Surgeons. I am a consultant to Cytyc Surgical Products.

4. I graduated with honors from Tufts University School of Medicine in Boston, Massachusetts, in 1987. I then completed a residency in radiation oncology in 1992 at the Mallinckrodt Institute of Radiology at Washington University Medical Center in St. Louis, Missouri, where I served as chief resident in radiation oncology. During my residency, I developed a computer-based training system for radiation oncology. I was also an American Cancer Society research fellow.

5. Prior to joining Cedars Medical Center, I worked as a radiation oncologist at another cancer center in Miami Beach, Florida. Before moving to Florida, I served as medical director for radiation oncology for Sharp Healthcare in San Diego.

6. My professional affiliations include serving as a member of the Cedars Medical Center Cancer Committee, as the cancer liaison physician to the American College of Surgeons, and as a member of the finance committee of the American Brachytherapy Society. I am also a member of The American Society of Therapeutic Radiation Oncology, American College of Radiology, ESTRO, Fletcher Society, American Radium Society, American College of Radiation Oncology, Association of Freestanding Radiation Oncology Centers, and the American Brachytherapy Society.

7. A copy of my curriculum vitae, which sets forth my background and experience in more detail, is attached as Exhibit A.

8. Over the past several years, accelerated partial breast irradiation, or APBI, as it is called, has developed as a viable option to traditional breast conservation therapy, which involves

irradiating the whole breast with conventional fractionated doses over a longer period of time. An increasing acceptance of APBI by the worldwide medical community, and ultimately proof of its equivalence to whole breast irradiation, critically depend, however, on careful selection of candidates for APBI from the patient pool and careful treatment delivery of those who are selected. Only through carefully selected patient candidates and careful treatment delivery can the medical profession accumulate scientifically convincing data regarding the benefits and efficacy of APBI.

9. Accordingly, it is vital that companies who introduce treatment delivery systems for APBI not market them for uses that are contraindications, i.e., situations in which the device should not be used because the risk of use clearly outweighs any possible benefit, or for uses that are inconsistent with warnings, i.e., limitations placed on use because of serious adverse reactions and potential safety hazards associated with the device. For example, if a newly introduced treatment delivery system is predicated on its equivalence and similarity to another treatment delivery system that has already been on the market, then it is difficult to see how the indications and warnings for the newly introduced treatment delivery system can be any different than those for the existing treatment delivery system, especially if there is no data to support expanded claims or indications.

10. An example is the warning that appears on the labeling for the Mammosite and Contura treatment delivery systems: "Do not use if the cavity is too small or if a skin surface to balloon surface distance of less than 5 mm will result." This warning is there for an important reason. The medical concern is not only about skin necrosis resulting from an unacceptably high dose at the skin, but also from the pressure effect from the brachytherapy balloon where the overlying tissue is thin. In other words, skin dose and pressure effect can potentially equally contribute to skin necrosis.

11. Accordingly, in my professional opinion, it is troubling that training presentations for the Contura treatment delivery system make the claim that Contura delivers the same skin dose at a two millimeter distance from the balloon surface to the skin surface that Mammosite delivers at an eight millimeter distance. This erroneously implies without any supporting data that Contura is safer than Mammosite for skin surface to balloon surface distances of less than five millimeters because the medical concern is not only about skin dose but also pressure effect.

12. The broad claim that the Contura treatment delivery system can treat patients who are candidates for APBI but are currently excluded because of the location of the lesion relative to breast size is also troubling, in my professional opinion. It goes without saying that the medical community as a whole applauds the introduction of treatment delivery systems that hold the promise of greater treatment flexibility or versatility. But candidate selection and evaluation is and should be performed on an individual-by-individual basis. Generalizations made by a company regarding whether a particular treatment delivery system can be used with a different or broader patient pool are overstated and unhelpful. What the medical community needs is information that will allow each professional to evaluate the appropriateness of a particular treatment delivery system for each patient, and each patient to make an informed decision about whether to choose APBI.

13.When a Mammosite balloon applicator is used for breast brachytherapy, the brachytherapy balloon is expanded so that its outer surface presses against and reshapes the resection cavity. This is what creates the pressure effect described above. If a balloon applicator were used to deliver localized radiation to brain tissue, however, one would not want to expand a brachytherapy balloon in this manner because the pressure effect could injure the sensitive brain tissue. In the breast, When the skin tissue over the balloon is thinner than 5 millimeters the blood supply may be inadequate to tolerate the pressure. Currently little information is available in this setting.

I declare that the foregoing is true and correct to the best of my knowledge under penalty of perjury.

Executed on April ___, 2008 in Miami, Florida.

_____

Martin E. Keisch, M.D.

Filer's Attestation

I, Katharine Altemus, am the ECF User whose identification and password are being used to file this Declaration of Martin E. Keisch, M.D. in Support of Plaintiffs' Motion for Preliminary Injunction. Pursuant to General Order No. 45, § X(B), I attest under penalty of perjury that concurrence in the filing of the document has been obtained from Martin E. Keisch, M.D..

Dated: April 7, 2008

By: */s/ Katharine Altemus*
Katharine Altemus